

Amendments to the Claims

1. (currently amended) A method of treating pain or alcohol abuse, providing opioid reversal ~~therapy, or maintaining opioid addicts or opioid maintenance therapy to a patient~~ comprising administering a therapeutic amount of ~~an opioid~~ a drug condensation aerosol ~~to the patient by inhalation,~~
wherein the drug is selected from the group consisting of fentanyl, naltrexone, buprenorphine, naloxone, butorphanol, hydromorphone, oxycodone, methadone, remifentanyl and sufentanyl, and
wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and having an MMAD of less than 5 microns. ~~3 µm and less than 5% opioid drug degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol.~~

2. (currently amended) The method ~~of~~ according to claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns. ~~wherein said condensation aerosol is formed by~~

- a. ~~volatilizing an opioid under conditions effective to produce a heated vapor of the opioid;~~
- and
- b. ~~condensing the heated vapor of opioid to form condensation aerosol particles.~~

3. (currently amended) The method according to claim 2 ~~1~~, wherein ~~said administration results in a peak plasma~~ drug concentration of said opioid is reached in less than 0.1 hours.

4. (cancelled)

5. (currently amended) The method according to claim 3 ~~1~~, wherein the ~~administered~~ condensation aerosol is formed at a rate greater than 0.5 mg/second.

6. (original) The method according to claim 1, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

7.-10. (cancelled)

11. (currently amended) The method according to claim 7 1, wherein said ~~the~~ therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.01 mg/L and 0.8 mg/L when delivered comprises between 0.01 mg and 0.8 mg of fentanyl delivered in a single inspiration.

12. (currently amended) The method according to claim 7 1, wherein said ~~naltrexone~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 15 mg/L and 35 mg/L when delivered comprises between 15 mg and 35 mg of naltrexone delivered in a single inspiration.

13. (currently amended) The method according to claim 7 1, wherein said ~~buprenorphine~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.1 mg/L and 1 mg/L when delivered comprises between 0.1 mg and 1 mg of buprenorphine delivered in a single inspiration.

14. (currently amended) The method according to claim 7 1, wherein said ~~naloxone~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.05 mg/L and 3.5 mg/L when delivered comprises between 0.05 mg and 3.5 mg of naloxone delivered in a single inspiration.

15. (currently amended) The method according to claim 7 1, wherein said ~~butorphanol~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.1 mg/L and 3 mg/L when delivered comprises between 0.1 mg and 3 mg of butorphanol delivered in a single inspiration.

16. (currently amended) The method according to claim 7 1, wherein said ~~hydromorphone~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.1 mg/L and 10 mg/L when delivered comprises between 0.1 mg and 10 mg of hydromorphone delivered in a single inspiration.

17. (currently amended) The method according to claim 7 1, wherein said ~~oxycodone~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.5 mg/L and 10 mg/L when delivered comprises between 0.5 mg and 10 mg of oxycodone delivered in a single inspiration.

18. (currently amended) The method according to claim 7 ~~1~~, wherein ~~said methadone~~ the therapeutic amount of a drug condensation aerosol has an inhalable aerosol mass density of between 0.25 mg/L and 20 mg/L when delivered comprises between 0.25 mg and 20 mg of methadone delivered in a single inspiration.

19. (currently amended) A method of administering ~~an opioid~~ a drug condensation aerosol to a patient ~~to achieve a peak plasma drug concentration rapidly~~, comprising administering the drug condensation aerosol to the patient by inhalation, ~~an aerosol of an opioid having less than 5% opioid~~ wherein the drug is selected from the group consisting of fentanyl, naltrexone, buprenorphine, naloxone, butorphanol, hydromorphone, oxycodone, methadone, remifentanyl and sufentanyl, and wherein the drug condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns. ~~3 microns wherein the peak plasma concentration of the opioid is achieved in less than 0.1 hours.~~

20. (cancelled)

21. (currently amended) A kit for delivering a drug condensation aerosol comprising:
a) ~~a.~~ a thin coating of an opioid composition and layer containing the drug, on a solid support, wherein the drug is selected from the group consisting of fentanyl, naltrexone, buprenorphine, naloxone, butorphanol, hydromorphone, oxycodone, methadone, remifentanyl and sufentanyl, and
b) ~~b.~~ a device for providing the condensation aerosol, wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns. dispensing said thin coating as a condensation aerosol.

22. (cancelled)

23. (currently amended) The kit ~~of~~ according to claim 21, wherein the device ~~for dispensing said coating of an opioid composition as an aerosol~~ comprises:
(a) ~~a.~~ a flow through enclosure containing the solid support,

(b) ~~contained within the enclosure, a metal substrate with a foil-like surface and having a thin coating of an opioid composition formed on the substrate surface;~~

(e) b. a power source that can be activated to heat the ~~substrate to a temperature effective to volatilize the opioid composition contained in said coating~~ solid support, and

(d) c. ~~inlet and exit portals~~ at least one portal through which air can be drawn ~~through said device~~ by inhalation,

wherein ~~heating the substrate by activation of the power source is effective to produce a vapor of the drug, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol.~~ form an opioid vapor containing less than 5% opioid degradation products, and drawing air through said chamber is effective to condense the opioid vapor to form aerosol particles wherein the aerosol has an MMAD of less than 3 microns.

24. (currently amended) The kit according to claim 23, wherein the heat for heating the ~~substrate~~ solid support is generated by an exothermic chemical reaction.

25. (currently amended) The kit according to claim 24, wherein ~~said~~ the exothermic chemical reaction is oxidation of combustible materials.

26. (currently amended) The kit according to claim 23, wherein the heat for heating the ~~substrate~~ solid support is generated by passage of current through an electrical resistance element.

27. (currently amended) The kit according to claim 23, wherein ~~said substrate~~ the solid support has a surface area dimensioned to accommodate a therapeutic dose of the drug, ~~an opioid composition in said coating.~~

28. (currently amended) The kit according to claim 21, ~~wherein a peak~~ wherein peak plasma drug concentration of ~~opioid is obtained~~ is reached in less than 0.1 hours ~~after delivery of the condensation aerosol to the pulmonary system.~~

29. (currently amended) The kit ~~of~~ according to claim 21, further including instructions for use.

30. (new) The method according to claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

31. (new) The method according to claim 2, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
32. (new) The method according to claim 19, wherein the drug is fentanyl.
33. (new) The method according to claim 19, wherein the drug is naltrexone.
34. (new) The method according to claim 19, wherein the drug is buprenorphine.
35. (new) The method according to claim 19, wherein the drug is naloxone.
36. (new) The method according to claim 19, wherein the drug is butorphanol.
37. (new) The method according to claim 19, wherein the drug is hydromorphone.
38. (new) The method according to claim 19, wherein the drug is oxycodone.
39. (new) The method according to claim 19, wherein the drug is methadone.
40. (new) The method according to claim 19, wherein the drug is remifentanyl.
41. (new) The method according to claim 19, wherein the drug is sufentanyl.
42. (new) The kit according to claim 21, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
43. (new) The kit according to claim 21 wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.
44. (new) The kit according to claim 42, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
45. (new) The kit according to claim 21, wherein the drug is fentanyl.

- 46. (new) The kit according to claim 21, wherein the drug is naltrexone.
- 47. (new) The kit according to claim 21, wherein the drug is buprenorphine.
- 48. (new) The kit according to claim 21, wherein the drug is naloxone.
- 49. (new) The kit according to claim 21, wherein the drug is butorphanol.
- 50. (new) The kit according to claim 21, wherein the drug is hydromorphone.
- 51. (new) The kit according to claim 21, wherein the drug is oxycodone.
- 52. (new) The kit according to claim 21, wherein the drug is methadone.
- 53. (new) The kit according to claim 21, wherein the drug is remifentanyl.
- 54. (new) The kit according to claim 21, wherein the drug is sufentanyl.
- 55. (new) The kit according to claim 23, wherein the solid support has a surface to mass ratio of greater than 1 cm² per gram.
- 56. (new) The kit according to claim 23, wherein the solid support has a surface to volume ratio of greater than 100 per meter.
- 57. (new) The kit according to claim 23, wherein the solid support is a metal foil.
- 58. (new) The kit according to claim 57, wherein the metal foil has a thickness of less than 0.25 mm.